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Four Stamford Plaza
P.O. Box 120
Stamford, CT 06904-0120
203-327-1700
Fax 203-351-4535
www.cl-law.com

Greenwich
Hartford
New Haven
Bonita Springs
Naples
Palm Beach

R. Thomas Payne
203-351-4192
tpayne@cl-law.com

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Prior Application: 08 09/934,121
Examiner: Church, C.
Art Unit: 2876

Assistant Commissioner for Patents
Box Continuation
Washington, D.C. 20231

Sir:

This is a Request for filing a continuation-in-part
 X continuation
 divisional

application under 37 CFR 1.53 of prior application Serial No. 09/934,121, filed on September 19, 1997, entitled **AN INTERMEDIATE DENSITY MARKER AND A METHOD FOR USING SUCH A MARKER FOR RADIOGRAPHIC EXAMINATION** by the following named inventor(s):

Full Name of Inventor	Family Name Russell	First Given Name Donald	Second Given Name G.
Residence & Citizenship	City Kensington	State or Foreign Country Connecticut	Country of Citizenship U.S.
Post Office Address	Post Office Address 86 Windsor Road	City Kensington	State & Zip Code/Country Connecticut 06037

1. Enter the amendment previously filed on January 6, 1999 under 37 CFR 1.116 in the prior application.

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2. A preliminary amendment is enclosed. By way of this Preliminary Amendment, Claims _____ in the prior application have been canceled (without prejudice).
3. The filing fee is calculated on the basis of the claims existing in the prior application *as amended at 1 and 2 above*.
- X 4. The filing fee is calculated on the basis of the claims existing in the subject application.

Large Entity

Claims	(1) For	(2) Number filed	(3) Number extra	(4) Rate	(5) Calculations
	Total Claims			X \$ 18.00	\$
	Independent Claims			X \$ 78.00	\$
	Multiple Dependent Claim(s) (if applicable)			+ \$ 270.00	\$
			Basic Fee		+ \$ 760.00
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				Other	\$
				TOTAL	\$

Small Entity

Claims	(1) For	(2) Number filed	(3) Number extra	(4) Rate	(5) Calculations
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			Basic Fee		\$ 380.00
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				Other	\$
				TOTAL	\$419.00

 X The Commissioner is hereby authorized to charge fees under 37 CFR 1.16 and 1.17 which may be required, or credit any overpayment to Deposit Account No. 11-0231. **A duplicate copy of this sheet is enclosed.**

 X A check in the amount of \$419.00 is enclosed.

 A new Oath or Declaration is included since this application is a continuation-in-part which discloses and claims additional matter.

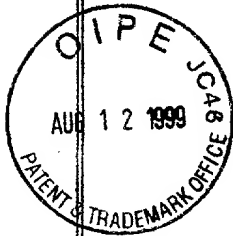
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AN INTERMEDIATE DENSITY MARKER AND A METHOD USING
SUCH A MARKER FOR RADIOGRAPHIC EXAMINATION

BACKGROUND OF THE INVENTION

5 This application is a continuation-in-part of co-pending Application Serial
No. 059,201, filed May 7, 1993.

10 The present invention relates generally to the field of radiography and,
more particularly, to a marker of intermediate density and a method of radiographic
examination using such a marker. The invention further relates to a system of
radiographic markers for use in such a method.

15 To convey pertinent information on radiographic film, radiologists and
technicians frequently use markers which absorb xrays and cast a shadow when
placed within the xray exposure field. Such markers are positioned either directly on a
patient undergoing radiographic examination or on the cassette holding the
radiographic film.

20 For example, right and left markers are routinely used to designate the
anatomical orientation of the patient or to identify a particular extremity being
examined. Markers are also used in trauma cases to localize the trauma site by
placing the marker on the skin surface at the appropriate location prior to xray
exposure. Further, markers are often placed on the surface of the examination table or
the film cassette, within the exposure field but outside the image of the patient, to
define the patient's physical orientation in relationship to the xray beam or the film, i.e.,
erect, prone, supine or decubitus.

in the past, radiographic markers have been constructed of materials having a high atomic number such as, for example, lead, mercury, steel or heavy metal salts. When exposed to xrays, markers having such high density completely attenuate the xray beam and cast a distinct shadow that is readily apparent on the xray film. The disadvantage here is that any tissue detail that falls within the shadow of the marker will be completely obscured. Metallic markers also create problems when employed in computerized tomography (CT) applications. CT scanners, which typically operate in the range of 60 to 80 KV, cannot tolerate the presence of metallic objects in the radiographic field. Such dense objects cause streaking which degrades the radiographic image. This problem is made more acute by the fact that the marker must have sufficient surface area to be imaged in at least one section radiographed by the scanner. A metallic marker having the required surface area would completely disrupt the scanning apparatus.

Accordingly, it has been the practice of those skilled in the art of general radiography to place such markers on the patient or the radiographic film outside the area of clinical concern. This practice encourages increasing the size of the xray field to ensure that the image of an important marker appears on the film. Unfortunately, one result of such a practice is that the patient's body is exposed to potentially harmful radiation beyond the specific site being examined. In cases where a radiographic examination is conducted and the image of a marker is not clearly visible within the exposure field, the exam is often repeated to either enlarge the exposure field or to reposition the marker. Again, the unfortunate result is that the patient is exposed to greater dosage of potentially harmful radiation.

To precisely locate a tissue area of particular concern on the radiographic film following exposure, there are circumstances where a marker is placed on a patient and purposely imaged while overlying anatomical structures. In such a case, it is the usual practice of those skilled in the art to use a small, metal,

spherical marker measuring no more than about 1 to 2 mm in diameter. While the shadow from such a small marker is less likely to obscure important tissue detail, the shadow may be mistaken for a physiological calcification or an opaque foreign body. Further, because such a marker is necessarily of small size with a correspondingly small shadow, there is an inherent difficulty in discerning variations in the size and shape of the marker's image on the film. Thus, the information that can be conveyed by markers of this type is limited.

Finally, markers comprising lead, mercury and other toxic heavy metals cannot be deposited in landfills or incinerated and thus present a potential environmental hazard if improperly disposed of. This problem is exacerbated by the fact that during radiographic examination procedures markers are often contaminated by body fluids. While contaminated markers can be sterilized, to save time and expense they are, more typically, discarded after only a single use.

It is therefore an object of the invention to provide a radiographic marker which may be placed on a tissue structure and imaged without obscuring underlying anatomical detail.

It is a further object of the invention to provide such marker which is constructed from non-toxic material.

It is a still further object of the invention to provide markers of this type in various sizes and shapes to convey pertinent information on radiographic film.

It is another object of the invention to provide a marker for use in CT applications which may be placed on a tissue structure and imaged without obscuring underlying anatomical detail.

It is yet another object of the invention to provide a method of radiographic examination using such markers.

SUMMARY OF THE INVENTION

5 The present invention meets these and other objects by providing a partially radiolucent, partially radiopaque marker for the radiographic examination of underlying tissue structures. The marker has a radiographic density and thickness selected to permit the marker to both cast a radiographic shadow and transmit sufficient radiation to image anatomical detail present in the tissue structure when the marker and the tissue structure are exposed to an xray beam.

10 In a second aspect, the invention provides a method for radiographic examination which includes the steps of providing a source of xray radiation capable of generating an xray beam of sufficient energy to image a tissue structure exposed to the beam, and positioning the above-described intermediate density marker between the source of the xray radiation and the tissue structure. Once the marker has been properly positioned, the marker and the tissue structure are exposed to the xray beam to generate a radiographic image of the structure with the shadow of the marker superimposed thereon. Since the radiographic density and thickness of the marker have been carefully selected to meet the criteria set forth above, anatomical detail present in the tissue structure is clearly visible through the shadow cast by the marker.

15 In another aspect, the present invention provides a system of intermediate density markers for use in the radiographic examination of tissue structures representing a range of tissue densities. Tissues representing the range of densities for which the markers comprising the system may be used include, for example: breast tissue and other soft tissues having a density approximately equal to that of water; intermediate density tissues, such as the bones of the extremities; and very dense tissues such as the skull, spine and the tissues comprising the chest and other thick body parts.

25 Each of the markers comprising the system has a radiographic density and thickness which permit the marker, upon exposure of the marker and an underlying tissue

structure to xray radiation of a specified energy, to both cast a radiographic shadow and transmit sufficient radiation to image anatomical detail present in the underlying tissue structure.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a radiograph of several rubber collars useful in practicing the method of the present invention imaged on the surface of a mammography phantom.

Figure 2 is a radiograph of rubber, aluminum and vinyl markers useful in practicing the method of the present invention imaged on the surface of the American College of Radiology quality assurance phantom.

Figure 3 is a cranio-caudal view of a patient's left breast with a vinyl marker useful in practicing the method of the invention positioned on the surface thereof.

Figure 4(a) is a posterior view of a plastic/barium sulfate marker useful in practicing the method of the present invention radiographed on the surface of a patient's foot.

Figure 4(b) is an oblique view of the marker shown in Figure 4(a).

Figure 5 is a radiograph of a plastic/barium sulfate marker useful in practicing the method of the present invention imaged on the surface of a patient's skull.

Figure 6 is a perspective view of a marker useful for practicing the method taught of the invention.

Figure 7 is a radiograph of the marker illustrated in Figure 6 imaged on the surface of a CT phantom.

DETAILED DESCRIPTION OF THE INVENTION

The most important factor regarding the detail recorded in a radiographic image is the disparity in light and dark or shadow intensity between adjacent objects. This is called image contrast and refers to the difference in the optical density between areas or objects imaged on a detector, commonly photographic film. As xrays pass through a patient, or other objects, they are absorbed, to varying degree, by the materials through which they pass. The principal determinant of contrast is the radiation attenuation property of each material, which is a function of the material's elemental and chemical composition. Materials of higher atomic number and density (weight per volume) have a greater ability to absorb xrays and reduce or attenuate the beam.

In the diagnostic xray spectrum, for example, bone, rich in calcium, contrasts very well with the surrounding muscle and other soft tissues which have a density equivalent to water. Fatty tissue, which is only 10% less dense than muscle, is not clearly distinguished from other soft tissues because of the lack of a significant attenuation differential.

These same conditions hold for all chemical compounds and mixtures, biological and non-biological.

Image contrast, as recorded radiographically, may be expressed mathematically, for a given spectrum of xrays, as follows:

$$C = (D2 - D1) / D1$$

Where C = the optical contrast differential between objects D1 and D2 as recorded on a radiograph.

Where D2 = the attenuating ability of object D2.

Where D1 = the attenuating ability of an adjacent object or the background attenuation.

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If a thin, uniform, moderate attenuator is placed in the xray beam, the overall quantity of xray in its path is uniformly and moderately reduced. Applied to the contrast equation shown above, this additional uniform attenuation shows up as an equal quantity in the numerator and the denominator. Mathematically, then, these additional figures cancel out and, C, representing the contrast differential between D2 and D1 is unchanged.

Utilizing these principles, the present invention provides a partially radiolucent, partially radiopaque marker having a uniform density and thickness for use in radiographic examination. Depending on the density of the particular tissue structure being examined and the corresponding radiation energy required, the density and thickness of the marker are selected so that upon exposure of the marker and an underlying tissue structure to the radiation, the marker will cast a legible shadow on radiographic film without obscuring radiographic anatomical detail present in the underlying tissue structure.

With regard to the range of tissue densities presented in human diagnostic radiology and the corresponding radiation energies required, those skilled in the art are well aware that soft tissue, such as breast tissue and other tissues having a density approximately that of water, require the application of "soft" radiation, generally in the range of from about 20 KV to about 40 KV. More dense tissue, such as bone tissue in the extremities, requires radiation in the range of from about 40 KV to about 70 KV. Finally, very dense tissue such as, for example, the skull, spine and the tissue structures comprising the chest, require more intense radiation in the range of from about 70 KV to about 120 KV.

Accordingly, the present invention encompasses markers of varying density and thickness which may be used for the radiographic examination of tissues representing the broad range of tissue densities noted above. In general, a marker is designed to absorb from about 2% to about 75% of the incident radiation. However, it

must be appreciated that the invention is in no way limited in this regard and that the markers may absorb more or less radiation depending on the particular tissue being imaged and its density. The governing parameters are that the marker must exhibit sufficient radiolucency to provide a discernible image when exposed to radiation and at the same time exhibit sufficient radiopacity so as not to obscure the underlying tissue detail.

Thus, it is no longer necessary, as with prior art radiographic markers and methods of examination, to completely attenuate the xray beam to achieve a consistent and easily discernible image of the marker on the film. As explained more fully below in connection with the Figures, there is a broad range of materials of intermediate density which can be used to construct the markers taught by the invention.

Referring now to Figure 1, a number of rubber O-shaped collars 10, 10 having a thickness of from about 1.5 mm to about 2 mm are shown radiographed on the surface of a Kodak mammography phantom 12. The exposure is at 28 KV, and the collars are equivalent to about 1.2 mm of aluminum, as established by the aluminum step wedge 14, which is graduated in 0.2 mm increments. Markers of this type are useful in imaging soft tissue at a radiation energy ranging from about 20 KV to about 40 KV and are particularly useful in mammography. As Figure 1 illustrates, the markers 10 have sufficient radiopacity to cast a discernible image and are sufficiently radiolucent to permit the simulated micro calcifications 16 and fine tissue details 18 to be clearly imaged.

Figure 2 illustrates additional examples of markers useful in radiographing low density tissue structures. The markers are constructed of rubber, aluminum and vinyl and are shown radiographed on the surface of the American College of Radiology quality assurance phantom ("ACR phantom 006 294"). The exposure is at 26 KV, and the radiograph was made using a photo-timed

mammography machine available from General Electric. As is well-known to those skilled in the art, the ACR phantom 20 approximates breast tissue density and has simulated calcifications and nylon low density "nodules".

Markers 22, 22 comprise strips of rubber having a thickness of about 0.2 inches and a density approximately equal to 0.115 inches of aluminum. Markers 24, 24 also comprise strips of rubber, and the strips have a thickness of 0.1 inches. Markers 26, 26 comprise plastic strips having a thickness of about 0.1 inches, and markers 28, 28 are strips of aluminum having a thickness of 0.115 inches. Finally, markers 30, 30 are strips of vinyl 0.1 inches thick.

As Figure 2 illustrates, markers comprised of these various materials cast a legible shadow without obscuring underlying detail when exposed to radiation energies typically employed in radiographing low density soft tissue. Generally, rubber markers having a thickness of from about 0.2 inches to about 0.4 inches are appropriate for radiographing soft tissue. With respect to plastic and aluminum markers, thicknesses ranging from about 0.1 inches to about 0.2 inches and from about .011 inches to about .022 inches, respectively, have been found useful. Vinyl markers provided in thicknesses ranging from about 0.75 mm to about 1 mm have been found useful.

The utility of markers constructed from vinyl for radiographing soft tissue structures without obscuring underlying detail is further illustrated in Figure 3. Figure 3 is a cranio-caudal view of a patient's left breast 32 with a vinyl marker 34 positioned on the surface thereof to mark the location of scar tissue. As Figure 3 illustrates, the anatomical detail in the breast tissue directly underlying the anterior marker 34 is clearly visible on the radiograph.

Figure 4 illustrates posterior and oblique views of a plastic/barium sulfate marker useful for radiographing more dense tissues at energy levels from about 40 to about 70 KV. The marker 36 is plastic impregnated with 40% barium, and it is shown

imaged on the surface of a patient's foot 38. Note that the anatomical detail in the bone 40 underlying the marker 36 is clearly visible.

Markers constructed of barium impregnated plastic have been found to be particularly useful in practicing the present invention because the density of the markers can be easily and precisely selected by varying the barium content of the plastic. Thus, an entire selection or system of barium impregnated plastic markers is provided for the entire range of tissue densities and exposure energies typically encountered by those skilled in the art.

Figure 5 shows a plastic/barium sulfate marker useful for radiographing very dense tissues, such as the bones of the skull, face and hip, at energy levels from about 70 to about 120 KV. The marker 42 is plastic impregnated with 40% barium and is cut from sheets measuring between 0.15-0.02 inches in thickness. The marker 42 is shown imaged on the surface of a patient's skull 44, and the radiograph shows that the marker images well at one to two layers of the sheet material (0.015-0.040 inches). The marker is most useful at a thickness of about 0.030-0.040 inches where it has sufficient density to be clearly visible on the radiograph, and yet permit sufficient penetration of the radiation to provide imaging of the diagnostic object contrast.

Figure 6 illustrates an intermediate density marker 46 useful in CT scanning applications. The marker 46 is shown imaged on the surface of a CT phantom 47 in Figure 7. The CT phantom 47 is available from the General Electric Corporation under the designation GE #46-241-85-2GI. The marker comprises a vinyl strip 48 having a plurality of apertures 50 formed therein. When the marker is imaged together with an associated tissue structure, the apertures indicate, as illustrated in FIG. 7, whether the marker is in the axial plane and also indicates whether the CT cut is high, through the middle or low with an accuracy of plus or minus about 1 mm. In addition, the apertures provide a site for needle insertion.

5 The strip 48 is preferably from about 1 mm to about 4 mm in thickness, from about 1 cm to about 4 cm in width and from about 5 cm to about 20 cm in length. In the illustrated embodiment, the strip 48 is about 2 mm thick, about 2 cm wide and about 8 cm long. The apertures 50, 50 are about 1 cm in diameter and are space about 0.5 cm apart. As those skilled in the art will appreciate, the length, width and thickness of the strip may be varied as long as it is large enough to image clearly.

10 Markers constructed from a number of different materials and suitable for radiographing tissues representing a broad range of densities have been illustrated above. Those skilled in the art will recognize, however, that there are a great number of other marker configurations as well as other materials, either alone or in combination, which are of an intermediate density and which could just as easily be used to practice the present invention.

15 As noted above, the density and thickness of the marker is selected based on the density of the tissue being examined and the energy of the radiation being applied. In general markers are designed to absorb from about 2% to about 75% of the incident radiation. For example, in certain CT applications, the marker is constructed to absorb as little as from about 2% to about 5% of the incident radiation. Again, the governing parameters are that the marker must absorb enough radiation to cast a legible shadow without obscuring underlying anatomical detail.

20 Additional factors that influence the ultimate choice of the material from which the marker is constructed include the cost of the material, its toxicity and the ease with which the marker can be manufactured. It must also be emphasized again that the selected material must be of a uniform density so that the radiographic image of the marker has a uniform, translucent appearance without visible irregularities, conflicting striations or granulations which might obscure the resolution of anatomical
25 detail.

The present invention further contemplates a system of partially radiolucent, partially radiopaque markers which are provided in a range of densities and thickness so that selected markers comprising the system may be used in radiographing tissue structures representing the various tissue densities enumerated above at the corresponding radiation energy range. In addition, the markers are provided in a variety of shapes to enhance the information communicated by the markers. In this regard, the markers may be shaped in accordance with a universal language, wherein each marker conveys a specific, universally accepted message. Such an enhancement of the information visibly communicated by the markers will expedite film interpretation and improve accuracy. For example, markers provided in the shape of an arrow, a triangle, the universal symbol of danger, or a standard medical cross could be provided to indicate an area of clinical concern on the film.

While preferred embodiments have been shown and described, various modifications and substitutions may be made without departing from the spirit and scope of the invention. Accordingly, it is to be understood that the present invention has been described by way of example and not by limitation.

CLAIM:

1. A method for radiographic examination comprising the steps of:
providing a source of xray radiation capable of generating radiation of
sufficient energy to image a tissue structure exposed to the radiation;
selecting a partially radiolucent, partially radiopaque marker having a
radiographic density and thickness which permit the marker to both cast a
radiographic shadow and transmit sufficient radiation to image anatomical detail
present in the tissue structure when the marker and the tissue structure are exposed to
the xray radiation;
positioning the marker between the source of the xray radiation and the
tissue structure, and
exposing the marker and the tissue structure to the xray radiation to
generate a radiographic image of the tissue structure having the shadow of the marker
superimposed thereon, wherein anatomical detail present in the tissue structure is
clearly visible through the shadow of the marker.
2. The method of claim 1 wherein the step of selecting the marker is
further characterized in that the marker has a radiographic density and thickness
which permit the marker to absorb from about 2% to about 75% of the xray radiation.
3. The method of claim 1 wherein the step of providing a source of
xray radiation is further characterized in that the source is capable of generating xray
radiation having an energy in the range of from about 20 KV to about 40 KV, and the
step of selecting the marker is further characterized in that the marker has a
radiographic density and thickness which permit the marker to absorb form about 2%
to about 75% of said energy.

4. The method of claim 1 wherein the step of providing a source of xray radiation is further characterized in that the source is capable of generating xray radiation having an energy in the range of from about 40 KV to about 70 KV, and the step of selecting the marker is further characterized in that the marker has a radiographic density and thickness which permit the marker to absorb from about 2% to about 75% of said energy.

5. The method of claim 1 wherein the step of providing a source of xray radiation is further characterized in that the source is capable of generating xray radiation having an energy in the range of from about 70 KV to about 120 KV, and the step of selecting the marker is further characterized in that the marker has a radiographic density and thickness which permit the marker to absorb from about 2% to about 75% of said energy.

6. The method of claim 1 wherein the step of selecting the marker is further characterized in that the marker comprises a barium impregnated plastic.

7. The method of claim 3 wherein the step of selecting the marker is further characterized in that the marker comprises a material selected from the group consisting of rubber, plastic, aluminum and vinyl.

8. The method of claim 4 wherein the step of selecting the marker is further characterized in that the marker comprises plastic impregnated with 40% barium by weight.

a polymeric material

9. A method for radiographic examination comprising the steps of:
providing a source of xray radiation capable of generating radiation in
an energy range of from about 20 KV to about 120 KV to image a tissue structure
exposed to the radiation;

5 selecting a partially radiolucent, partially radiopaque marker having a
radiographic density and thickness which permit the marker to absorb from about 2%
to about 75% of the xray radiation, wherein the marker both casts a radiographic
shadow and transmits sufficient radiation to image anatomical detail present in the
tissue structure when the marker and the tissue structure are exposed to the xray
10 radiation;

positioning the marker between the source of the xray radiation and the
tissue structure, and

exposing the marker and the tissue structure to the xray radiation to
generate a radiographic image of the tissue structure having the shadow of the marker
15 superimposed thereon, wherein anatomical detail present in the tissue structure is
clearly visible through the shadow of the marker.

10. A system of radiographic markers for use in the radiographic
examination of tissue structures representing a range of tissue densities, said system
comprising a plurality of partially radiolucent, partially radiopaque markers, wherein at
least one of each of said markers comprising the plurality has a radiographic density
5 and thickness which permit the marker, upon exposure of the marker and an
underlying tissue structure to xray radiation of a specified energy, to both cast a
radiographic shadow and transmit sufficient radiation to image anatomical detail
present in the tissue structure underlying the marker.

11. The system of markers of claim 10 wherein each of the markers has a density and thickness which permit the marker to absorb from about 2% to about 75% of the xray radiation.

12. The system of markers of claim 10 including a plurality of barium impregnated plastic markers, wherein the density of each of said markers is determined by the amount of barium comprising said marker.

13. The system of claim 10 wherein the xray radiation has an energy of from about 20 KV to about 40 KV and the markers comprise materials selected from the group consisting of plastic, rubber, vinyl and aluminum.

14. The system of claim 10 wherein the xray radiation has an energy of from about 40 KV to about 70 KV and the markers comprise a plastic impregnated with 40% barium by weight.

15. A partially radiolucent, partially radiopaque marker for radiographic examination, said marker having a density and thickness such that upon exposure of the marker and an underlying tissue structure to xray radiation of specified energy, the marker casts a legible shadow on radiographic film without obscuring radiographic anatomical detail present in the underlying tissue structure.

16. The marker of claim 15 wherein the marker has a density and thickness which permit the marker to absorb from about 2% to about 75% of the xray radiation.

17. The marker of claim 15 wherein the xray radiation has an energy of from about 20 KV to about 40 KV and the marker comprises a material selected from the group consisting of plastic, rubber, vinyl and aluminum.

18. The marker of claim 17 wherein the marker comprises barium impregnated plastic.

19. The marker of claim 15 wherein the xray radiation has an energy of from about 40 KV to about 70 KV and the marker comprise a plastic impregnated with 40% barium by weight.

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ABSTRACT

The present invention provides a partially radiolucent, partially radiopaque marker and a method for using such a marker for radiographic examination. The marker and the disclosed method may be employed for the examination of tissue structures of various densities. The radiographic density and thickness of the marker are selected so that when the marker and an underlying tissue structure are exposed to xray radiation of a specified energy, the marker casts a legible shadow without obscuring anatomical detail present in the underlying tissue structure. The invention also provides a system of partially radiolucent, partially radiopaque markers for use in the method of radiographic examination taught by the invention.

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In re Application of: RUSSELL, Donald G.)

) Examiner: C. Church

Serial No.: 09/934,121)

) Group Art Unit: 2876

Filed: September 19, 1997)

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A Method Using Such A Marker For)
Radiographic Examination)

Assistant Commissioner for Patents

Washington, D.C. 20231

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Dear Sir:

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Date: June 8, 1999



Joseph S. Kentoffio, Reg. No. 33,189
Attorney for Applicant(s)
CUMMINGS & LOCKWOOD
CityPlace I, 185 Asylum Street
Hartford, CT 06103
Tele: (860) 560-5912